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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,453	03/15/2006	Hartmut M. Hanauske-Abel	601-1-135PCT	9573

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,453	HANAUSKE-ABEL ET AL.	
	Examiner	Art Unit	
	LEI YAO	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *4-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed on 8/19/2010 in response to the previous Non-Final Office Action (2/17/2010) is acknowledged and has been entered.

Claims 1-43 are pending.

Claims 4-43 have been withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species.

Claims 1-3, drawn to a diagnositc ligand binding to hypusine-containg form of eIF5A, wherein the hypusin is located at amino acids 35-65 of SEQ ID NO: 1 and 2, are under consideration.

Rejections Withdrawn

1. The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Bergeron et al., (J. Med. Chem., 1998, 41 (20), pp 3888–3900) is withdrawn in view of the amendment to the claims reciting antibody binding to a hypusine-containing eIF5A.

2. The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Ruhl et la., (The Journal of Cell Biology, 1993, Vol. 123, pages 1312-1320) is withdrawn in view of the amendment and applicant's argument.

Accordingly, applicant's arguments regarding the rejections set forth on page 12-13 of the remarks are moot.

Rejection Maintained and Response to Arguments

Rejection under 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 remain rejected under 35 U.S.C. 102(b) as being anticipated by Beninati et al (FEBS Letters, 437: 34-38, 1998) and Claim 1 remain rejected under U.S.C. 102(b) as being anticipated by Xu et al (Jan, 2001, JBC, 276, 2555-2561) for the following reason:

Applicant amends base claim 1 to a diagnostic ligand binding to a hypusine containing form of eIF5A, and hypusine occurring in a sequence spanning residues 35-65 of SEQ ID NO: 1 or 2. The amended claims require a diagnostic ligand comprising an antibody binding to eIF5A that contains hypusine occurring in sequence spanning residues 35-65 of SEQ ID NO: 1 and 2. The term "diagnostic" is preamble and intended use of the claimed ligand, which is given no patentable weight since for claimed product the body of the claim does not depend on the preamble for completeness, instead, structural limitations in the claims are able to stand alone.

See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The antibody disclosed by Beninati et al recognizes the hypusine containing eIF5A (figure 1B, western blot), therefore still meets the limitation of amended claims.

The RNA disclosed by Xu et al binds to the hypusine region of eIF5A and still meets the limitation of the claimed ligand.

Applicant provides the following general arguments regarding all rejections under USC 35 102 and current amendment (page 11).

Applicant argues that the resent claims embrace a diagnostic ligand that interacts with a hypusine-containing eIF5A with post translational hydroxylated form of the protein, which is distinct as a result of enzymatic incorporation of a single oxygen atom into the modified lysine (deoxyhypusine). Applicant states that claimed ligand interacts with a subpopulation of eIF5a that is distinct from the prior art (page 11).

In response, the claims as written, do not distinct the structure of hypusine as a single oxygen atom from the regular hypusine understood by and disclosed in the art. Both the specification (page 2 or paragraph 7 and figure 2) and the art disclose the same structure of hypusine that is a modified Lysine residue by posttranslational modification (Beninati et al, page 20950, left col, line 1). The reason for giving no patentable weight to the preamble "diagnostic" ligand is provide as set forth above.

Applicant also provides following arguments regarding the reference by Beninati et al, FEBS Letters 437:34-38 (page 13, subtitle 3).

Beninati et al do not teach hydroxylation status of eIF5A which antibody binds to. Figure 1 shows metabolic labeling for hypusine formation and immunologic labeling for eIF5A synthesis. Based on last paragraph of section 3.1 of the result, "the data showed an about 30% decrease of the intensity of the eIF5A band..." Beninati et al do not teach or suggest a ligand including antibody that binds to eIF5A in a manner depending on eIF5A hydroxylation.

In response, the claims as written, recite antibody or a ligand binding to hypusine containing form of eIF5A, which is clearly taught in figure 1B. The claims do not require

the antibody binding to the hypusine region of the protein and not require hydroxylation status of eIF5A. Hydroxylation is one step of the process in formation of hypusine eIF5A, but not a product. The claims merely encompass antibody binding to the hypusine containing form of eIF5A. The Beninati's antibody per se has the properties of the claimed antibody or ligand, the courts have held that if the product (antibody) in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In re Thorpe., 227 USPQ 964, 966 (Fed. Cir. 1985): In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983). Thus, Applicant's arguments have not been found persuasive, and the rejection is maintained.

Applicant also provides following arguments regarding the reference by Xu et al, JBC, 276:2555-2561 (page 14, subtitle 4).

Xu do not teach or suggest the diagnostic ligand presently claimed. The intention of applicants is not to claim all ligands bind to hydroxylated eIF5A but ligands for diagnosis of human diseased and for tissue response to therapeutic. Exposure of eIF5A to random sequence RNA ligand is not used for diagnosis of biomarkers.

In response, the claims amended from a ligand to a diagnostic ligand do not change the scope of the invention because term "diagnostic" is preamble of intended use of the ligand, which is given no patentable weight as set forth above. Thus, Applicant's arguments have not been found persuasive, and the rejection is maintained.

Applicant further provides current publication to support patentability of the claimed ligands (page 14, subtitle 5).

Applicant cites recent publication (exhibit B, Hoque et al) showing inhibition of hypusination of eIF5A by antifungal drug Ciclopirox, an inhibitor of deoxyhypusine hydroxylase, and then states that this occurs in strict congruency with applicant prior publication showing labeling hypusine formation (bridging page 14-15). Applicant again argues the references of Bergeron and Ruhl et al (page 15, line 8+), which is moot since the rejections are withdrawn. Finally, Applicant organizes the references provided by the Office and applicant in a table (bridging page 16).

In response, first, recent and previous applicant publications teach a method of using antifungal drug Ciclopirox to inhibit function of enzyme deoxyhypusine hydroxylase for formation hypusine. None of the references teaches that Ciclopirox binds to eIF5A protein or as a ligand interacting with the protein. None of the references teaches that the drug Ciclopirox could bind to hypusine contained eIF5a to detect the presence of hypusine in eIF5A as well as being used for the purpose of diagnostic agent. As such, the references do not teach or support the claimed ligand that binds to hypusine containing eIF5A. Second, the Office reject the claims under USC 102 that is art rejection. Provided reference does not seem to help applicant to overcome the art rejections since the references do not provide evidence showing that the ligand or antibody disclosed in the art do not interact or bind to the hypusine contained eIF5A. In another word, provided recent and previous applicant publications could not disqualify the art used in the 102 rejection. The Office appreciates applicant's organization of the arts presented in the application. The references used in the standing 102 rejections have been discussed as set forth above.

Conclusion

No claim is allowed.

Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao/
Examiner, Art Unit 1642

/Misook Yu/
Supervisory Patent Examiner, Art Unit 1643